

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

CASSAVA SCIENCES, INC.,

Plaintiff,

v.

DAVID BREDT, GEOFFREY PITT,
QUINTESSENTIAL CAPITAL
MANAGEMENT LLC, ADRIAN HEILBUT,
JESSE BRODKIN, ENEA MILIORIS and
PATRICK MARKEY,

Defendants.

Case No. 1:22-cv-09409-GHW-OTW

ORAL ARGUMENT REQUESTED

**REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS
DR. JESSE BRODKIN, DR. ADRIAN HEILBUT, AND DR. ENEA MILIORIS'S
MOTION TO DISMISS THE FIRST AMENDED COMPLAINT**

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Cassava’s Opposition ignores both the context of the Dot.com Defendants’ statements and the controlling case law that says context matters. It utterly fails to grapple with the law that makes these statements, published in the midst of heated scientific, regulatory, and popular discourse, non-actionable expressions of opinion. (*Infra* Section I.) With equal disregard for the law, the Opposition fails to apply any viable theory of actual malice. (*Infra* Section II.) And, it attempts to erase Cassava’s own admissions of scientific error that defeat its premise of falsity. (*Infra* Section III.) Finally, the Opposition attempts a 365-page backdoor amendment of the Complaint, conceals or mischaracterizes the numerous retractions and corrections associated with the science underlying simufilam, and attempts a bizarre and indefensible pivot towards defamation “by implication.” (*Infra* Section IV.)

Essentially, Cassava invites the Court to imagine a world in which Cassava’s own pronouncements about its experimental drug candidate automatically become scientific consensus and incontrovertible facts. Any contrary view, Cassava asks the Court to believe, is necessarily false and must be motivated by a nefarious conspiracy. But that is not how scientific discourse works, and it is not how defamation law works.

I. THE STATEMENTS ARE NON-ACTIONABLE EXPRESSIONS OF OPINION¹

The law of defamation specifically forecloses “sifting through a communication for the purpose of isolating and identifying assertions of fact,” as Cassava’s Opposition and Appendix seek to do. *Valley Elecs. AG v. Polis*, No. 21-2108-CV, 2022 WL 893674, at *1 (2d Cir. Mar. 28, 2022). Rather, the Court must consider the “broader written and social contexts” at issue—which are the “key considerations in categorizing a statement as fact or opinion.” *Id.* Hence, the Court’s task is to consider challenged statements in context and “holistically” to determine

¹ Citations to the “FAC” and “Ex.” refer to the First Am. Compl. (Dkt. 30) and Exhibits (Dkts. 30-1 to 39-6) and citations to “Mot.” and “Opp.” refer to the opening brief (Dkt. 87) and opposition brief (Dkt. 95).

whether, in the minds of reasonable readers, the statements conveyed facts or opinions. *Hayashi v. Ozawa*, No. 17-CV-2558, 2019 WL 1409389, at *3 (S.D.N.Y. Mar. 28, 2019) (collecting cases rejecting a “mechanical” approach to the fact-opinion analysis).

A. Cassava Fails to Address the Broader Written and Social Contexts

Cassava asks the Court to ignore many layers of context. The Opposition ignores the inherent uncertainty associated with any experimental new drug undergoing clinical stage testing. That baseline uncertainty is amplified here by the intense public scrutiny of simufilam and other Alzheimer’s drugs. It is heightened further by the many investigations related to simufilam, including by CUNY, SEC, DOJ, and NIH. (Mot. 2-7.) The Opposition and FAC disregard all of this. Cassava posits a fictional context where the science concerning simufilam is settled and truth is determined by company press releases, but the Court need not accept this.

Cassava also ignores that other scientists (including the Citizen Petition Defendants) have expressed their own independent concerns about the research underlying simufilam, and did so before the Dot.com Defendants. By suing three sets of critics, Cassava seeks both to blur the three separate groups together into a grand conspiracy and to suggest that *all* criticism of Cassava and simufilam is associated with these Defendants. Both of those ideas are wrong: each Defendant is part of the context of the other Defendants’ statements, and there are many others who have levelled similar criticisms.² In truth, Cassava faces intense criticism because it has failed to credibly defend its incongruous scientific claims. There is no conspiracy, only the reality of widespread criticism.

² See, e.g., Dr. Elisabeth Bik, “Cassava Sciences: Of stocks and blots,” *Science Integrity Digest* (Aug. 27, 2021), <https://scienceintegritydigest.com/2021/08/27/cassava-sciences-of-stocks-and-blots/>; Apoorva Mandavilli, “Scientists Question Data Behind an Experimental Alzheimer’s Drug,” *The New York Times* (Apr. 18, 2022), <https://nyti.ms/3vEFVED>

The Opposition fails to escape the logic of the Second Circuit’s opinion in *ONY*. (Opp. 13 (citing *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013).) Cassava admits, as it must, that *ONY* protects scientific debate. Instead, Cassava argues that the “publications are defamatory not because they debated science, *but because they accused Cassava of intentionally faking the science.*” (*Id.*) But, at least in this case, this is an artificial distinction. The science at issue is not an abstract set of conclusions with which Drs. Brodtkin, Heilbut, and Milioris happen to disagree. Rather, it is the flawed research methods, retracted articles, false public denials of any methodological issues (followed by limited public acknowledgements of errors), admitted “re-do” of the phase 2b analysis (with selectively limited data), and so forth. (Mot. 3-7.) Hence, there is no meaningful distinction between “the science” and the methods employed. Because the scientific debate and allegedly defamatory accusations are inextricably intertwined, this is precisely the type of case that *ONY* cautions courts against trying to referee. *ONY*, 720 F.3d at 497.

B. Cassava Fails to Identify Actionable Statements of Fact or Mixed Opinion

Cassava tries and fails to convert the statements into assertions of fact or mixed opinion.

First, Cassava argues that readers interpret statements as factual when they claim to be based on a “thorough investigation.” (Opp. 10-11.) This argument lacks any legal support. If accepted, it would prioritize unfounded attacks over well-sourced criticism and deter disclosure of investigatory work. For good reason, courts focus on whether statements are accompanied by their factual bases, not whether they claim to be based on an investigation. *See Eros Intl. PLC v. Mangrove Partners*, 2019 WL 1129196, at *7 (Sup. Ct. N.Y. County Mar. 8, 2019).³

³ Cassava cites inapposite cases. *See Gross v. New York Times Co.*, 82 N.Y.2d 146 (1993) (relying largely on newspaper’s decision to publish accusations in “news” section, rather than “opinion” section); *Flamm v. Am. Ass’n of Univ. Women*, 201 F.3d 144 (2d Cir. 2000) (involving “ambulance chaser” accusation in an otherwise “fact-laden” and “straightforward directory” of attorneys).

Second, Cassava claims that the Dot.com Defendants’ status as scientists lent “credibility to their defamatory assertions about Cassava” and signaled to readers that they were “conveying assertions of fact.” (Opp. 11.) This is exactly the facile concept of science that the Second Circuit rejected in *ONY*. See 720 F.3d at 496 (recognizing that although science is understood to deal in “verifiable facts,” the “essence of the scientific method [is] that the conclusions of empirical research are tentative and subject to revision”). Cassava cites no case where a court held that a defendant’s profession made the challenged statements more likely to be deemed factual by reasonable readers. And for good reason: if this were the law, speech by those without expertise would enjoy more protection than speech by professionals.

Third, Cassava claims the Dot.com Defendants’ calls for investigations “encouraged readers to believe their statements were factual because a scientist does not rely on conjecture and opinion to call for action.” (Opp. 11-12.) But the weight of the case law interprets calls for an investigation to signal the opposite—namely, expressions of opinions. See, e.g., *Brian v. Richardson*, 87 N.Y.2d 46, 54 (1995); *Silvercorp Metals Inc. v. Anthion Mgmt. LLC*, No. 150374/2011, 2012 WL 3569952, at *2 (Sup. Ct. N.Y. County Aug. 16, 2012); *Sandals Resorts Int’l Ltd. v. Google, Inc.*, 925 N.Y.S.2d 407, 414 (1st Dep’t 2011).⁴

Fourth, Cassava claims the “entire scheme was predicated on convincing readers that they were presenting facts, not opinions” because “[i]nvestors do not make trading decisions based on conjecture or speculation,” but rather, “based on facts.” (Opp. 12.) It defies reality to suggest that the stock market is driven entirely by facts and devoid of opinion. This argument is

⁴ Cassava attempts to distinguish *Sandals* on the basis that, here, the challenged statements called for an investigation “only after” making accusations of misconduct. (Opp. 12.) But the “accusations” and calls for an investigation were both included in the FDA Letter (Ex. 6), and Cassava’s argument only illustrates its failure to consider the publications holistically.

also contrary to the case law holding that short sellers' disclosures of their short positions signal to readers that they are expressing opinions, not facts. (Mot. 20.)

Finally, the Opposition claims that the challenged statements should be actionable as "mixed opinions" because they (i) included "factually inaccurate" statements; and (ii) "failed to disclose material facts." (Opp. 14-15.) But Cassava does not show falsity. Rather, it merely paraphrases each challenged statement, often misleadingly, and then adds a conclusory assertion that the statement was wrong. (*See, e.g.*, FAC ¶ 162 ("Cassava did not rely upon any fabricated, manipulated, or doctored research in connection with developing simufilam"); *id.* ¶ 399 ("Defendants failed to disclose that none of the results that they characterize as 'unusual' or 'suspicious' or 'dubious' are actually 'unusual,' 'suspicious,' or 'dubious.'").) A flat, conclusory denial does not render a statement actionable.

Cassava also misapplies the legal standard (Opp. 15), which considers whether the statement implied to a reasonable reader that it was based on undisclosed facts—not (as Cassava argues) whether the defendant "failed to disclose" every fact contrary to the opinion. (*See* Mot. 19.) Even if that were the standard, Cassava relies on conclusory allegations, and ignores the Dot.com Defendants' descriptions and disclosures of their factual sources, including via hyperlinks directly to the source materials. (*See, e.g.*, Ex. 10 at 17, 28; Ex. 12 at 9.)

II. THERE IS NO PLAUSIBLE BASIS TO INFER ACTUAL MALICE

Cassava attempts to plead actual malice inferentially based on allegations that the Dot.com Defendants failed to consider "contradictory evidence"; "lacked evidence" to support their claims; disregarded the "inherently improbable" nature of their claims; and "purposefully avoided" the truth. (FAC ¶¶ 290-365; Opp. 15-19.) But actual malice cannot be inferred from these allegations, where, as is the case here, the statements concern unsettled questions about an

experimental new drug. Even in the imaginary context of a long-settled debate, the FAC provides no basis to infer actual knowledge of falsity or a reckless disregard of the truth.

“Contradictory information.” Cassava purports to rely on allegations that the Dot.com Defendants reviewed journal articles supporting the foundational research for simufilam and the testing protocols used by Cassava to test simufilam. (Opp. 16-17 (citing FAC ¶¶ 308-315).) However, these allegations fail for two reasons. *First*, the allegedly disregarded “evidence” includes the very journal articles whose questionable methods and conclusions lie at the heart of this debate. (FAC ¶ 308.) *Second*, the alleged refusal to give credence to “contradictory” journal articles does not permit an inference of actual malice, particularly given the inherent uncertainty associated with any experimental new drug in clinical testing. Cassava’s argument lacks any supporting case law, and, if adopted, would chill scientific discourse by allowing an inference of actual malice anytime someone challenged peer-reviewed research.⁵

“Lack of evidence.” Cassava’s assertion that the Dot.com Defendants lacked evidence (Opp. 17) to support their claims is belied by the face of the challenged publications, which meticulously describe the evidentiary bases for their opinions. The Opposition focuses on the concerns in FDA Letter (Ex. 6) about exposing study participants to “incalculable risk with unknown consequences,” and Dr. Brodtkin’s subsequent post stating, “I’ll give you that we don’t know that it isn’t safe.” (Opp. 17.) These two statements are consistent, as both explicitly acknowledge the uncertainty over simufilam. But even if there were some inconsistency, there still would be no basis to infer actual malice. When the FDA Letter is considered holistically

⁵ The simple context and “contradictory evidence” in *NOVAGOLD* are nothing like the context and “contradictory evidence” at issue here. *NOVAGOLD Res., Inc. v. J Cap. Rsch. USA LLC*, No. 20-CV-2875, 2022 WL 900604, at *9 (E.D.N.Y. Mar. 28, 2022). In that case, a short-seller published a report accusing a mining company of misleading investors by *inter alia* concealing a gold mine’s \$8 billion price tag. The company sued for defamation and pled actual malice based on the short-seller’s alleged failure to consider “contradictory evidence”—namely, that the company had, in fact, disclosed the \$8 billion price tag.

and in context, it is clear that the “risks” to patients were based on the painstakingly detailed concerns about Cassava’s credibility and simufilam’s underlying research. (*See* Ex. 6.)

“Inherently improbable” and “purposeful avoidance.” Cassava claims the Dot.com Defendants’ accusations were “inherently improbable” because they were inconsistent with “common knowledge in the scientific community.” (Opp. 17-18.) Cassava again fails to recognize that an experimental drug in clinical testing, by definition, involves unsettled questions, not “common knowledge.” Moreover, the Opposition claims the Dot.com Defendants had a duty to consult Cassava directly before criticizing the company. (Opp. 18-19 (citing FAC ¶¶ 331–346).) But no such duty exists. Neither of Cassava’s two inapposite cases suggests otherwise. *See Harte-Hanks Commc’ns, Inc. v. Connaughton*, 491 U.S. 657, 658 (1989) (involving a newspaper article that accused a political candidate of bribery where newspaper disregarded the “most important witness to the bribery charges”); *NOVAGOLD*, 2022 WL 900604 at *9 (mentioning defendant’s failure to make follow-up inquiries of mining company where defendant had a “lack of experience covering mining companies”).

Finally, all that remains are Cassava’s conclusory assertions that the Dot.com Defendants’ profit motives as short sellers permit an inference of actual malice. (Opp. 15-16.) But profit motives are often at play in defamation cases and as a matter of law are never enough, standing alone, to plead actual malice. *See, e.g., MiMedx, Inc. v. Sparrow Fund Mgmt. LP*, No. 17-CV-7568, 2018 WL 4735717, at *12 (2d Cir. Mar. 28, 2022); *Kipper v. NYP Holdings Co.*, 12 N.Y.3d 348, 356 (2009). Indeed, profit was central to *ONY*, which involved rival pharmaceutical companies fighting over the findings of a study commissioned by one of the companies and then published in a scientific journal; unsurprisingly, the study touted the benefits of the commissioning company’s product over the rival company’s product. Nevertheless, the

Second Circuit held that such debates, concerning a “novel area of research,” fall outside the reach of defamation law. *See ONY*, 720 F.3d at 497. The same is true here.

III. THE OPPOSITION DOES NOT SAVE CASSAVA’S FALSITY THEORY

The Opposition dodges the admissions by Cassava and its lead researchers of errors in simufilam’s underlying research—admissions that defeat the FAC’s falsity allegations. (Opp. 7-8; *see* Mot. 14-16.) For instance, the Opposition does not deny that published research contains erroneous and mislabeled visual data, but nevertheless claims that “Cassava does not concede . . . that its data contain ‘indicia of manipulation’.” (Opp. 8.) The Opposition bizarrely ignores that Cassava itself conceded the “indicia of manipulation,” including, most notably, the CEO’s admission of “visual errors” (Ex. 104 at 8) and Drs. Burns and Wang’s admission of errors in their 2017 article. (Mot. 6.) What remains is a dispute over the Defendants’ *interpretation* of what the errors represent (*i.e.*, the possibility of scientific fraud) versus Cassava’s competing *interpretation* (*i.e.*, honest mistakes). The errors are undisputed, only their meaning is in dispute. Drs. Brodtkin’s, Heilbut’s, and Milioris’ interpretations are not *false*—they are interpretations.

IV. THE OPPOSITION IS PROCEDURALLY IMPROPER AND MISLEADING

First, the Opposition’s 365-page Appendix displays both disregard for the Court’s rules and Cassava’s failure to confront the statements in context or holistically. As required, the undersigned counsel disclosed the grounds of this Motion to Cassava’s counsel in advance of filing and offered Cassava the opportunity to amend. Having declined to amend then, Cassava should not be allowed to reverse course and amend now via the backdoor of its Appendix. Moreover, each entry in the Appendix reflects an improper attempt to de-contextualize the Dot.com Defendants’ statements—contrary to the requirements of the law.

Second, the Opposition paraphrases and selectively quotes the Dot.com Defendants’ publications. In effect, it is a series of attacks on straw men. For example, Cassava claims the

Dot.com Defendants “[s]tated that Cassava coordinated an elaborate scheme of lies to gain approval for their drug candidate.” (Opp. 6; *see also* Opp. 10.) But “elaborate scheme of lies” is Cassava’s phrase, not the Dot.com Defendants’. And, Cassava’s citation is to a single isolated phrase from the Dot.com Defendants’ 23-page FDA Letter (Ex. 6) alleging “a pattern of deliberate, coordinated misconduct.” (Opp. 6.) Cassava ignores the adjacent paragraph of the FDA Letter, which explained that “what follows is a description of the methods by which, *we allege*, Cassava Sciences has either obfuscated or fabricated data during these clinical trials.” (Ex. 6 at 2.) Cassava also fails to appreciate that, in the FDA Letter, the Dot.com Defendants painstakingly recited the bases for their views (*id.* at 3-24); raised “key questions” to be addressed (*id.* at 5, 6, 13, 17, 22, and 23); and called on the FDA to conduct a “thorough investigation” (*id.* at 24). Cassava repeats this tactic again and again: it embellishes or distorts the Dot.com Defendants’ actual language, and it willfully ignores context. (Opp. 6-7, 10-13.)

Third, the Opposition ignores (or misrepresents) the expressions of concern, corrections, or retractions of papers authored by simufilam’s lead researcher, Dr. Wang. (*See* Mot. 4-6.) For example, Cassava claims that “even the journals relied upon by the Dot.com Defendants . . . concluded that there was no ‘compelling evidence of data manipulation intended to misrepresent the results.’” (Opp. 17.) But Cassava ignores that the journal that issued the quoted statement (*Neurobiology of Aging*) went on to explain that it was deferring its final decision on appropriate corrective action until after CUNY’s investigation was complete.⁶ Cassava avoids addressing the seven retractions and numerous expressions of concern, hiding behind the assertion that such “extrinsic” evidence cannot be considered. (Opp. 8.) But that is wrong. The FAC incorporates

⁶ *Neurobiology of Aging*, “Expression of Concern: Wang et al., (2017) PTI-125 binds and reverses an altered conformation of filamin A to reduce Alzheimer’s disease pathogenesis. *Neurobiol. Aging*, 55:99-114” (May 2022), <https://doi.org/10.1016/j.neurobiolaging.2022.03.012>

the journal articles and responses (albeit by mischaracterizing them) and they may therefore be considered. (See FAC ¶¶ 300-01, Exs. 16-19; *see also* FAC App. A at 110 (referencing Aug. 16, 2022 post on Twitter listing retractions.)

Finally, at certain points Cassava appears to pivot toward a theory of defamation by implication. This pivot is improper because it is too late. *Wright v. Ernst & Young LLP*, 152 F.3d 169, 178 (2d Cir. 1998). It is also unavailing because a claim based on implication is subject to an even higher standard than one based on an express statement. *Biro v. Condé Nast*, 883 F. Supp. 2d 441, 466 (S.D.N.Y. 2012) (describing “especially rigorous” standard).

V. LACK OF PERSONAL JURISDICTION OVER DRs. BRODKIN AND MILIORIS

The Opposition fails to identify allegations in the FAC sufficient to establish personal jurisdiction over Drs. Brodtkin or Milioris, residents of New Jersey and England, respectively. Cassava attempts to assert jurisdiction, for the first time in its Opposition, based on Drs. Brodtkin and Milioris’s purported use of New York State’s FOIL. (Opp. 21-22.) However, the Opposition cites easily distinguishable, non-defamation cases, and not any cases where the use of NY’s FOIL was sufficient to establish jurisdiction.⁷ Moreover, the mere use of information that originated in New York is insufficient. (Opp. 21-22.) In the cases cited by Cassava, all or “virtually all” of the conduct giving rise to publication occurred in New York.⁸ None of Cassava’s other jurisdictional arguments overcome the deficiencies set forth in the Motion. (Mot. 10-13.)

⁷ *Trabucco v. Intesa Sanpaolo, S.p.A.*, 695 F. Supp. 2d 98, 104–105 (S.D.N.Y. 2010) (breach of contract action where performance and breach occurred in New York); *Arch Specialty Ins. Co. v. Ent. Specialty Ins. Servs.*, No. 04-CV-1852, 2005 WL 696897, *6 (S.D.N.Y. Mar. 24, 2005) (declaratory judgment action by insurance company)

⁸ *Legros v. Irving*, 327 N.Y.S.2d 371, 372–74 (1st Dep’t 1971) (“virtually all the work attendant upon publication of the book occurred in New York”); *Montgomery v. Minarcin*, 263 A.D.2d 665, 667 (3d Dep’t 1999) (same).

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